IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,	)	
Plaintiffs,	)	C.A. No. 18-823-CFC
v.	)	
EAGLE PHARMACEUTICALS INC.,	)	
Defendant.	)	

DEFENDANT EAGLE PHARMACEUTICALS INC.'S PROPOSED CONCLUSIONS OF LAW ON NON-INFRINGEMENT

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I. INTRODUCTION

In the Hatch-Waxman Act, "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). Par's conduct serves neither.

Rather, to extend its unwarranted monopoly over vasopressin, Par asserts invalid and fraudulently obtained[1] patents directed to ***Reformulated*** Vasostrict, to delay entry of Eagle's generic version of prior art ***Original*** Vasostrict, a formulation essentially identical to those used to treat hypotension for a century. To do so, Par stretches its claims to the point of absurdity, alleging infringement if the pH rises into the claimed range for as little as a few minutes, which admittedly provides no benefit to stability or otherwise.

Yet even with this scope, Par failed to meet its burden on infringement. *First*, binding Federal Circuit precedent holds that "[b]ecause drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug product in a manner that directly addresses the issue of

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[1] *See* Defendants' Proposed Conclusions of Law On Invalidity and Unenforceability, filed concurrently herewith.

infringement ***will control the infringement inquiry***."[2] *Abbott Lab'ys v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002). That is the case here: Eagle's ANDA specifications directly address the infringement issue by defining a non-infringing product with a pH ***outside*** the claimed range on release and at ***all*** times during the shelf life. (FF¶¶322–23, 334–36.) Numerous cases, such as *Elan* and *Brimonidine* discussed below, affirm this principle, which should end the inquiry. Inexplicably, however, Par does not even acknowledge this precedent. Instead, Par would have the Court focus on two far less relevant cases, *Sunovion* and *Tyco*, to disregard some of Eagle's specifications, (Pl. Br. at 21–22), and then look to only some of Eagle's data, ignoring the rest, to find infringement, (Pl. Br. at 25–26). Par does not cite any legal authority permitting this approach because there is none.

Second, in cases where it is appropriate to look beyond the specification, the patentee must prove "that the ANDA applicant 'would ***likely sell*** an infringing composition pursuant to an approved ANDA.'" *Ferring B.V. v. Watson Lab'ys, Inc.-Fla.*, 764 F.3d 1382, 1388 (Fed. Cir. 2014) (quoting *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1565 (Fed. Cir. 1997)). But here, Par points only to a single pH measurement (of over 340) from the first batch of ANDA Product (of over 12), made using an outdated process that existed before any of the Asserted Patents published or issued, that went out-of-specification and into the

[2] All emphasis added.

claimed range at the very end of its shelf life. (FF¶¶388–89.) The Federal Circuit has found such evidence insufficient as a matter of law. *See Ferring B.V. v. Watson Labs., Inc.-Fl.*, 764 F.3d 1401, 1405, 1409 (Fed. Cir. 2014) (finding four of "hundreds" of test results within claims cannot support infringement).

So instead, Par cobbles together a theory that tacks the maximum purported pH variability from Eagle's data onto the upper bounds of Eagle's specifications to speculate that at least some vials of Eagle's ANDA Product could "drift" into the claimed pH range. But the Federal Circuit has rejected such a hybrid analysis. *See In re Brimonidine Patent Litig.*, 643 F.3d 1366 (Fed. Cir. 2011) (reversing infringement finding based on analysis combining test data with specification limits). Par again provides no precedent for its novel theory, because none exists.

Even if Par's newfound theory had any merit, Par's infringement claims would separately fail because Par has not shown Eagle will directly or indirectly infringe. Eagle will not administer its ANDA Product to patients as required by the '209 Patent. And even under its "drift"/"variability" theory, Par offered no evidence Eagle's ANDA Product will have a pH in the claimed range—violating its specifications—when made or sold. That leaves Par to allege inducement, but it did not prove Eagle will have "specific intent" to induce others to infringe. To the contrary, Eagle has taken deliberate steps to ***avoid*** infringement.

Par's infringement case fails at every turn, and the Court should enter judgment of non-infringement for Eagle.

II. EAGLE'S ANDA SPECIFICATIONS MANDATE A FINDING OF NON-INFRINGEMENT

A party infringes when it practices each and every limitation of an asserted patent claim. *See Glaxo*, 110 F.3d at 1565. ANDA cases, however, are unique in that they concern an "artificial act of infringement that consists of submitting an ANDA" because, at the time of suit, the final product generally does not yet exist. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003). In such cases, courts conduct a "hypothetical inquiry" to determine whether the ANDA product would infringe if made. *See Glaxo*, 110 F.3d at 1569.

For this inquiry, the Federal Circuit has "distinguished between cases where the ANDA specification resolves the question of infringement and those where it does not[.]" *Par Pharm., Inc. v. Luitpold Pharm., Inc.*, 2017 WL 452003, at *6 (D.N.J. Feb. 2, 2017). When an "ANDA specification directly resolves the infringement question," the specification controls. *See Ferring*, 764 F.3d at 1408. In contrast, "[i]n cases in which the ANDA specification does not resolve the infringement question in the first instance," courts look to other relevant evidence, such as batch data, to determine whether the product likely to be sold pursuant to the ANDA will infringe. *Id*. at 1409.

Here, Eagle's ANDA indisputably defines a non-infringing product, which

should end the inquiry. Par, however, inexplicably fails to acknowledge or apprise the Court of this framework, instead proffering its own concoction—referred to at trial as the "*Sunovion/Tyco* theory," (Tr. 58:15–20)—based on two cases that bear almost no resemblance to this case.

A. Eagle's ANDA Specifications Define A Non-Infringing Product

Par cannot establish infringement as a matter of law because Eagle's ANDA defines a non-infringing product. "In some cases, the ANDA specification directly resolves the infringement question because it defines a proposed generic product in a manner that either meets the limitations of an asserted patent claim or is outside the scope of such a claim." *Ferring*, 764 F.3d at 1408. In such cases, "[t]he infringement case is [] limited to an analysis of whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed." *Warner-Lambert*, 316 F.3d at 1364. Thus, when an ANDA specification clearly defines a non-infringing product, "the specification in [the] ANDA ***mandates*** a finding of no literal infringement." *Bayer v. Elan*, 212 F.3d 1241, 1249 (Fed. Cir. 2000) ("*Elan*").[3]

[3] The Federal Circuit also has consistently applied the "specification controls" principle to the converse circumstance: when the specification defines an ***infringing*** product, infringement must be found. *See e.g.*, *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1274 (Fed. Cir. 2013) (finding infringement of claims requiring "less than 0.25% of [a] levorotatory isomer," despite defendant's promise not to release a product with less than 0.3% isomer, because ANDA sought approval for product containing 0.0–0.6% isomer);

Elan is directly on point. The patent there claimed crystals with a "specific surface area of 1.0 to 4 m^2/g." 212 F.3d at 1246. The defendant's ANDA called for crystals with a surface area greater than 5 m^2/g, outside the claimed range. *Id*. The Federal Circuit held that "under the ANDA specification, Elan cannot literally infringe" and "the specification in Elan's ANDA mandates a finding of no literal infringement." *Id*. at 1249.

Here, every asserted claim requires "a pH of 3.7–3.9." (FF¶¶332–23.) Eagle's ANDA, in contrast, specifies a release pH of "3.4–3.6," and a stability pH "same as release." (DTX-327.1; FF¶334.) Eagle thus seeks authorization only for a formulation with pH 3.4–3.6 on release and at ***all times*** during the shelf life. (FF¶335.) As in *Elan*, Eagle's ANDA mandates a non-infringement finding.

Par's contrary arguments are meritless.

First, Par contends the Court still must consider Eagle's testing data even though its ANDA defines a non-infringing product. But the Federal Circuit rejected that argument in *Brimonidine*. There, the asserted claims required a pH of ***7.0 or greater***, while the ANDA specified a ***maximum pH of 6.7***. 643 F.3d at 1376–77. The district court nonetheless found infringement by looking past the

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Abbott, 300 F.3d at 1374 (finding infringement because "the ANDA would seem to define the compound in a manner that directly addresses the question of infringement," despite defendant's argument that, in practice, the ANDA product would not meet the claims).

ANDA to test data showing a downward pH trend, concluding that, "[t]o produce a product that will maintain a pH" within the ANDA stability pH specification, the defendant "would necessarily manufacture its product at an infringing pH of 7.0 or above." *Id.* But the Federal Circuit reversed. After restating the "specification controls" principle of *Elan*, it concluded that "neither party disputes that if [defendant] complies with its ANDA, it will never manufacture or sell a product at a pH above 6.7." *Id* at 1378. It then rejected the district court's conclusion, stating "[w]e can't assume that [defendant] will not act in full compliance with its representations to the FDA." *Id.* at 1378.

The same is true here.[4] Dr. Kirsch conceded that "[a]ny batch that's compliant with the release [and] stability specification would not infringe." (Kirsch Tr. 298:9–12.) Because it would be improper to assume based on Eagle's test data that it "will not act in full compliance with" its pH specifications, Par cannot show infringement as a matter of law.

Second, Par claims *Sunovion* holds that Eagle's ANDA specifications should not control and the Court must consider testing data. But *Sunovion* does not help

[4] Par attempts to distinguish *Brimonidine* because it addressed data showing pH going down, not up. (Pl. Br. at 21 n.6.) That is a distinction without a difference. *Brimonidine* holds it improper to use batch data to contradict a clear ANDA specification, and to assume a specification violation will occur. *Id.* at 1378. That applies whether the pH goes up or down, or the specification is for release or stability. *See also* Section III.B, *infra*.

Par because the ANDA there ***defined an infringing product***. 731 F.3d at 1278–79. It was for that reason the defendant's promise not to infringe could not be accepted. *Id*. at 1278. The Federal Circuit has since held that "*Sunovion* only applies when 'an ANDA specification defines a compound such that it ***meets*** the limitations of an asserted claim,'" *Ferring*, 764 F.3d at 1387 (quoting *Sunovion*, 731 F.3d at 1280). That is not the case here.

Because Eagle's ANDA specifications define a non-infringing product, the inquiry need not proceed further.

B. The Court Need Not Consider Testing Data As A Matter of Law

Par's is wrong that the Court must consider Eagle testing data. Par not only ignores the "specification controls" caselaw, but also that the circumstances where the Federal Circuit has endorsed going beyond the specification do not apply here.

First, when "an ANDA is ***silent*** with respect to a claim limitation," considering data is appropriate because "it is the product that the generic company is ***likely to sell*** that guides the infringement analysis." *Par Pharm., Inc. v. Hospira, Inc.*, 835 Fed. App'x. 578, 586 (Fed. Cir. 2020) ("*Hospira*"); *see also Glaxo*, 110 F.3d at 1568. In *Glaxo*, the claims were directed to "Form 2" of a crystal, while the ANDA described a product with "99% pure Form 1" crystal. 110 F.3d at 1564. The Federal Circuit endorsed considering testing data only to determine whether the product contained traces of "Form 2" as an impurity (*i.e.*, in the remaining 1%),

which ANDA did not address. *Id.* at 1568. The Federal Circuit confirmed this principle in *Elan*: "the biobatch in *Glaxo* was properly considered because the ANDA specification in that case did not define the compound in a manner that directly addressed the issue of infringement." 212 F.3d at 1250; *see also Abbott*, 300 F.3d at 1375 (claim required "about 4–6 repeating subunits," while ANDA did not specify subunit number); *Ferring*, 764 F.3d at 1403 (claim required "dissolution release rate" per specific testing protocol, while ANDA did not measure rate per claimed protocol). In all these cases, the ANDA did not directly resolve the infringement question. Here, in contrast to those cases, Eagle's ANDA does.

Second, consideration of data can be appropriate, despite a non-infringing specification, when there is evidence of "an ***actual commercial product*** with actual test results" supporting infringement. *Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1346, 1349 (Fed. Cir. 2002). Here, in contrast, there is no Eagle commercial product, and Par and its expert Dr. Kirsch admitted they have no evidence of ***any*** batch manufactured using Eagle's ***optimized*** process meeting the claimed pH range. (*See* FF¶¶389, 397.) *Biovail* also is distinguishable because the Federal Circuit was reviewing grant of summary judgment of non-infringement, finding only that the "actual commercial product" meeting the claims raised a fact question regarding whether the ANDA product also would infringe. *Biovail*, 279 F.3d at

1342. The court did not create a blanket rule, as Par appears to suggest, that testing data must be considered despite an unambiguous specification. (Pl. Br. at 17–18.)

Par ignores these limited exceptions and instead relies on *Tyco Healthcare Grp. LP v. Mut. Pharm. Co., Inc.* for its statement that "it is ***not unreasonable*** for a patent owner to allege infringement under section 271(e)(2)(A) if the patent owner has evidence that the as-marketed commercial ANDA product will infringe, even though the hypothetical product specified in the ANDA could not infringe." 762 F.3d 1338, 1344 (Fed. Cir. 2014). *Tyco* is less relevant than *Elan*, *Brimonidine*, *Sunovion*, or *Abbott*, but if anything, supports Eagle.

Tyco was an appeal of an antitrust ruling determining whether an infringement suit was "objectively baseless." *Tyco*, 762 F.3d at 1343–44. Regarding the patent infringement suit, Par ignores that the district court ***granted a Rule 52(c) motion of non-infringement*** after finding the patent covered an "SSA" of "below 1.1[m^2/g]" while the ANDA specified an "SSA" of "at least 2.2[m^2/g]." *Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 2009 WL 2422382, at *3, *7 (D.N.J. Aug. 4, 2009). The court therefore asked "whether there was anything [Tyco, the patentee,] had not presented in regard to the question of infringement ***under Elan***, and Tyco answered in the negative." *Id.* Tyco did not appeal this ruling. Instead, the ***defendant*** appealed the grant of summary judgment against its antitrust claim, with the Federal Circuit merely stating that the patent suit was "not unreasonable,"

where Tyco had ***actual testing showing samples that infringed***. *Tyco*, 762 F.3d at 1342; *Tyco*, 2009 WL 2422382, at *5. Most relevant here, the Federal Circuit did ***not*** question the district court's reliance on *Elan* in granting the Rule 52(c) motion, nor suggest that Tyco's testing evidence could have carried the day. If anything, *Tyco* supports finding non-infringement based on Eagle's ANDA specifications—as was done there—particularly since Par lacks evidence showing Eagle's ANDA product as sold likely will infringe.

C. Par's Other Arguments Are Legally Irrelevant And Ignore Eagle's Stability Specification

Par raises several other arguments in an attempt to salvage its infringement claims, but none can overcome Eagle's non-infringing ANDA specification.

First, Par focuses solely on Eagle's ***release*** specification, painting Eagle's ***stability*** specifications—which it concedes define a non-infringing product (P-FF¶86)—as a mere goal "that drug products ***should meet***," but which in reality need not be met due to purported difficulties in policing and enforcement. (Pl. Br. at 6, 21.) Par considers this appropriate because, in its view, "Eagle's products still have a significant upward drift problem." (Pl. Br. at 24.) But Par cites no case permitting ANDA stability specifications—or indeed any ANDA specifications—to be ignored due to alleged enforcement difficulties. *Brimonidine* expressly considered both release and stability specifications, and leaves no room for Par's argument. 643 F.3d at 1377–78. Eagle is ***not*** seeking approval for a product that

can drift into the claimed range, (FF¶338), and Par has no evidence Eagle will be unable to, or otherwise will not, comply with all its specifications.

Second, Par argues that Eagle will test only "a small fraction of products pulled from a small subset of batches," and this "is inadequate to avoid a finding of infringement in the context of ANDA litigation." (Pl. Br. at 22.) But Par bears the burden on infringement, not the other way around. Par cites no law allowing it to assume Eagle will violate its ANDA specifications, while ample cases say it cannot. *Brimonidine*, 643 F.3d at 1378; *Ferring*, 764 F.3d at 1408. Nor did Par offer evidence that Eagle's proposed testing protocol is atypical. Extensive stability testing on 12 batches of vasopressin product show Eagle can and will comply with both its release and stability specifications. (FF¶¶386–406.)

Citing *Sunovion* again, Par suggests that a plaintiff cannot be expected to conduct its own post-launch testing to confirm a defendant's compliance with its shelf-life specifications. (Pl. Br. at 22–23.) But, as noted, *Sunovion* concerned an ***infringing*** ANDA specification and an ineffective promise to avoid the infringing parts of that specification. 731 F.3d. at 1279. The Federal Circuit rejected the defendant's argument that the plaintiff "could later test any of [defendant's] commercially available generic [] products … to monitor [defendant's] compliance" ***with its promise***, but only because that promise was legally irrelevant given the infringing specification. 731 F.3d. at 1279. As shown above, *Sunovion*

has no applicability when, as here, an ANDA defines a non-infringing product. Unlike the defendant in *Sunovion*, Eagle does not need to promise to avoid any portion of its ANDA pH specifications to not infringe, because the specification already is non-infringing. (*See* FF¶336.)

Third, Par relies on the Federal Circuit's comment in *Abbott* that "[i]t is also possible, at least in theory, that other evidence may directly contradict the clear representations of the ANDA." 300 F.3d at 1373. Par omits that the court first cited the "specification controls" case law, including *Elan*, with approval, and then stated that "[s]uch circumstances may be ***unlikely to arise in practice*** but, in any event, ***do not describe the case before us***." *Id*. That was because the ANDA there defined a product that ***met*** the disputed limitation, resolving the infringement question. *Id*. at 1374. *Abbott* thus supports that, when the ANDA specification resolves the infringement question, the inquiry ends. In *Abbott* that meant infringement; here it means non-infringement.

Lastly, Par argues that "[w]hether Eagle's product infringes Par's patents is not determined by the FDA; the FDA's concern is whether Eagle's product will be safe and effective." (Pl. Br. at 23.) That is irrelevant. Par has no authority suggesting Eagle can violate its pH specifications, which indisputably require a non-infringing pH. (FF¶¶334–38); *see Abbott*, 300 F.3d at 1373 ("Because drug manufacturers are bound by strict statutory provisions to sell only those products

that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry."). Moreover, Par has identified no rule requiring a non-infringing ANDA specification to "concern" the FDA in order to avoid patent liability. Finally, Par offered no regulatory expert at trial (although it had retained one for its case against Amneal); its unsupported attorney argument regarding "the FDA's concern" should be given no weight.

III. EAGLE'S BATCH DATA DO NOT SHOW A LIKELIHOOD OF INFRINGEMENT

If the Court looks past Eagle's ANDA specification, the data show that Eagle is ***not*** likely to sell an infringing product. When batch data are considered, the question is "what is ***likely*** to be sold following FDA approval," *Glaxo*, 110 F.3d at 1568; *Hospira*, 835 Fed. App'x. at 586. Under this inquiry, the Court must consider Eagle's entire process, including the in-process specifications, to determine the features of the actual product Eagle likely will sell. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Amneal Pharms. LLC*, 881 F.3d 1376, 1379–80, 1385 (Fed. Cir. 2018) (finding non-infringement after considering manufacturing processes). Par has the burden to prove infringement by a preponderance of the evidence. *Ferring*, 764 F.3d at 1408. It cannot meet that burden.

A. Par Has Not Shown That Eagle's Product Is More Likely Than Not To Reach pH 3.7–3.9

The testing data for Eagle's ANDA Product demonstrate it is not likely to infringe Par's patents. In cases where the specification does not answer the infringement question, "the relevant inquiry is whether the patentee has proven by a preponderance of the evidence that the alleged infringer will ***likely*** market an infringing product. What is ***likely*** to be sold, or, preferably, what ***will*** be sold, will ultimately determine whether infringement exists." *Glaxo*, 110 F.3d at 1569. In such cases, "it is proper for the court to consider the ANDA itself, materials submitted by the ANDA applicant in support of the ANDA, and any other relevant evidence submitted by the applicant or patent holder." *Elan*, 212 F.3d at 1248–49.

Par cannot meet its burden because the evidence shows it is exceedingly unlikely Eagle's ANDA Product will ever have the claimed pH. Of the 12 batches of its ANDA Product placed on stability, Eagle has taken pH measurements at ***344*** distinct time points from release to expiration. (FF¶388.) Of those, only ***one*** was out-of-specification ("OOS") and in the claimed pH range. (FF¶389.) That measurement was at the end of shelf life of SVA001, the first batch ever manufactured, using a different process from Eagle's proposed commercial process. (FF¶358, 361.)

(DDX2–18 (demonstrative); *see* DTX-993.1; DDX7-1.) SVA001 was manufactured by AMRI before Eagle's involvement, at a time when the release and stability pH specifications were much broader (between 2.5 and 4.5), and it does not represent the pH of Eagle's ANDA Product. (FF¶¶344–45, 350–52, 384.) At that time, the Asserted Patents had not even been published (much less issued), and there was no concern—as evidenced by the 2.5–4.5 pH specification—about maintaining pH 3.4–3.6. (FF¶346.)

After the Asserted Patents issued and Eagle partnered with AMRI, they narrowed the release and stability pH specifications to 3.4–3.6, thereby avoiding the claimed pH range entirely. (FF¶362.) When SVA001 subsequently exhibited the OOS pH result, Eagle conducted an investigation that showed the "root cause" was its release with a pH of 3.64, "the upper limit of the pH specification." (FF¶360.) That resulted in Eagle adding controls to the manufacturing process to

"ensure the pH remains within the established range during finished product manufacturing and through the proposed shelf life." (DTX-133.21; FF¶¶360–61, 374.) Those in-process optimizations included:

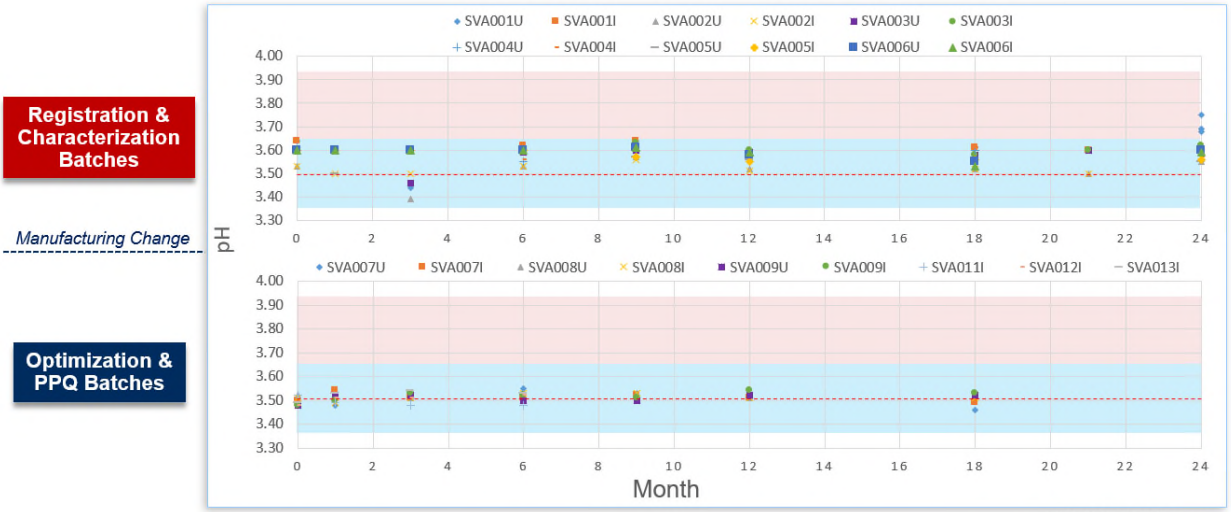
- Narrowing the specification for pH adjustment from 3.4–3.6 (for SVA001) to 3.42–3.49 (FF¶362);
- Adding a pH stabilization step requiring additional mixing and multiple pH measurements from 3.42–3.50, with specified measurements requiring pH values within 0.03 of each other (FF¶¶363–68); and
- Narrowing the in-process pH specifications (pre- and post-filtration) from 2.5–4.5 (for SVA001) to 3.42–3.54 (FF¶372).

These controls were designed to prevent products from being released "at the upper limit of the pH specification," (*i.e.*, 3.64), like SVA001 was, and instead ensure release toward "the middle of the pH specification (*i.e.*, 3.50)." (FF¶¶373–74.) They were also intended to ensure the product was thoroughly mixed for a more uniform product, to reduce variability. (FF¶¶369–70.)

The data show these optimizations were successful. Eagle's optimization batches SVA007, SVA008 and SVA009 all had pH values at release and over the 18-months of completed stability testing that "are closely around 3.50." (FF¶375.) Par does not contend these batches will rise into the claimed range before expiration. (*See generally* Pl. Br.; FF¶¶394–95.)

Furthermore, after optimization, the pH data show only minor, expected "variation occur[ing] around 3.50." (FF¶397; Park Tr. 378:19–79:10.) Comparing pH data for Eagle's un-optimized Registration and Characterization Batches (SVA001–006) with its optimized batches (SVA007–009, SVA011–013) shows this. The unoptimized batches had post-filtration, in-process pHs of 3.5–3.7, while every optimized batch had a pH of 3.44–3.50 at that stage. (FF¶398.) Similarly, unoptimized batches had release pHs spread between 3.53 and 3.64, while the optimized batches had pHs significantly lower, centered around 3.50, *i.e.*, 3.45–3.57. (FF¶399.)

Comparing pH stability data highlights the optimization's success:



(DDX2-19 (demonstrative); *see* DTX-993.1; DDX7-1.) The unoptimized batches had pHs across a very broad range of 0.31 pH units, from 3.44–3.75, while every optimized batch had a pH within a much narrower range centered around 3.50,

from 3.46–3.55. (FF¶400.) Contrary to Par's assertions, these data demonstrate Eagle's optimized manufacturing process has both lowered and tightened the pH, such that Par cannot show it is more likely than not to reach pH 3.7. (FF¶¶401, 403.)

Par's arguments against this overwhelming evidence stumble out of the blocks. *First*, Par's relies on the single, OOS pH measurement from SVA001. But reliance on such anomalies does not prove infringement by a preponderance of the evidence. *Ferring*, 764 F.3d at 1409. In *Ferring*, the district court found infringement based on data showing that four ANDA tablets met the claimed dissolution profile. *Id*. at 1409. The Federal Circuit reversed because it considered evidence of four infringing tablets among "hundreds of coated commercial products tested" insufficient to support infringement as a matter of law. *Id*.

In the best case for Par, this case is like *Ferring*. Par concedes it hangs its hat on one allegedly infringing OOS result from SVA001. (*See* Pl. Br. at 3–5.) It also concedes that all other samples, ***including all others from SVA001***, maintained the specified pH of 3.4–3.6 under all specified storage conditions and at all times through their shelf lives. (*See* Pl. Br. at 5; FF¶¶397–403.) Par does not contest the conclusion from Eagle's investigation that the lone OOS measurement for SVA001 resulted from release at the very upper limit of its specification (pH

3.64).[5] (*See* Pl. Br. at 3.) Indeed, Eagle has gone a step further than the *Ferring* defendants and optimized its manufacturing process to ensure batches are consistently produced with a release pH lower than 3.64. (FF¶¶373, 401.) The lone SVA001 result—***1 of 344***—is analogous to *Ferring*'s four of "hundreds," which were insufficient to support an infringement finding as a matter of law.[6]

Second, Par dismisses the mass of data showing non-infringement, likening this case to *Sunovion* and *Hospira*, (Pl. Br. at 15–16), but these comparisons fall flat. In both cases, the Federal Circuit was not looking at testing data to determine "what is likely to be sold following FDA approval," *Glaxo*, 110 F.3d at 1568,

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[5] Par disputes whether the SVA001 OOS result can be considered an "anomaly" like the tablets in *Ferring*, because it was investigated and explained. (Pl. Br. at 20 n.5.) That is irrelevant. As Par concedes, the defendant in *Ferring* found the coating for the four infringing tablets was "incomplete" and "lacked coating integrity," *Ferring*, 764 F.3d at 1409–10, and was thus a result of "the product itself" as well (Pl. Br. at 20 n.5). The Federal Circuit found non-infringement even without guarantees that such defective coatings would not recur. *Ferring*, 764 F.3d at 1409–10.

[6] Par contends that AMRI's corporate designee, Ronald Aungst, was "inconsistent" regarding whether AMRI would release a batch that failed in-process specifications but thereafter met release specifications. (Pl. Op. Br. at 7, n.2.) On the contrary, Aungst repeatedly and consistently testified that AMRI would ***not*** release a batch to Eagle that failed its in-process specifications, even if it subsequently met the release specifications. (*See* FF¶¶439, 484.) The purported "inconsistency" follows Par's counsel insisting that Aungst testify as to what the ***FDA*** would do ***if*** AMRI ***did*** release such a batch. (FF¶¶484.) Aungst appropriately answered that he did not know both because he cannot speak for the FDA, and because he had already testified that such a scenario ***would not occur***. (*Id*.)

because the specifications alone resolved the question in favor of infringement. *See Hospira*, 835 Fed. App'x. at 586 ("[U]nlike in *Ferring*, the ANDA is ***not silent*** as to whether Hospira's product could [infringe] . . . *Sunovion* therefore applies."). The court merely rejected the defendants' attempts to use extrinsic promises (*Sunovion*) or testing data (*Hospira*) to overcome an indisputably infringing specification. *Sunovion*, 731 F.3d at 1275; *Hospira*, 835 Fed. App'x. at 585–86. Thus, *Sunovion* and *Hospira* support Eagle, as they hold the Court need not look to batch data when the ANDA resolves the infringement question.

B. Par Improperly Combines Eagle's Release Specification And Actual Data, While Ignoring Eagle's Stability Specification

Having failed to provide any evidence that either: (1) Eagle's ANDA specifications, or (2) Eagle's testing data, show a likelihood of infringement, Par presents the legally impermissible infringement theory combining select portions of the specifications and data according to the following equations:

1. Upper end of the release specification (pH 3.64) + variability or drift data (as little as 0.01) = pH between 3.7–3.9 (Pl. Br. at 1, 7, 14–15, 19); or
2. Upper end of Eagle's in-process specification (pH 3.54) + maximum variability between in-process and release data (0.07) + maximum shelf life variability (0.06)[7] = pH between 3.7–3.9 (Pl. Br. at 17).

[7] Throughout its brief, Par repeatedly refers to this post-release variability as "drift." But the data for the post-optimization batches do not show any trend

This is nearly identical to the patentee's argument in *Brimonidine*, which the Federal Circuit rejected. 643 F.3d 1366. As discussed above, in *Brimonidine*, the patentee attempted to use expert testimony and test data to argue that, because the data showed the ANDA product would drift downward as much as 0.5 pH over its shelf life, it would necessarily need to be manufactured at a higher, infringing pH than its specification allowed, in order to stay within its pH stability specification. 643 F.3d at 1377. The Federal Circuit rejected the district court's intermingling of testing data with ANDA specifications, instead restating that the specification alone controls the infringement inquiry. *Id.* at 1378.

Par's approach here invites the same legal error; whereas the patentee in *Brimonidine* used testing data to argue the defendant would violate its release specification, here, the only difference is that Par attempts to use testing data to argue Eagle will violate its stability specification. Par's theory presents the sort of rank speculation the Federal Circuit has repeatedly rejected. *See*, *e.g.*, *id.* ("We cannot assume that Exela will not act in full compliance with its representations to the FDA."); *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, (Fed. Cir. 2012) (rejecting speculative argument that generic product would be prescribed

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towards upward drift, but rather minor fluctuation or variability up and down, centered around 3.50–3.52. (FF¶¶397–401, 422–423.) In fact, the only data for the post-optimization batches that show drift are the room temperature data, which show ***downward*** drift away from the claimed pH range. (FF¶402.)

contrary to its label carve outs); *Warner-Lambert*, 316 F.3d at 1364 (rejecting argument that generic product would be prescribed for patented use, stating "Section 271(e)(2) does not encompass 'speculative' claims of infringement.").

Par's theories also lack scientific merit. With respect to scenario 1, Par has not shown Eagle's optimized manufacturing process is likely to yield a release pH of 3.64. (FF¶¶399, 414, 425); *Glaxo*, 110 F.3d at 1568 ("what is likely to be sold following FDA approval" controls). Eagle's optimized manufacturing process was designed to avoid that result, and the data show it was successful. Nor is Eagle seeking approval for a product that may be released at 3.64 and then rise even as little as 0.01, which would violate its stability pH specification. (FF¶339.)

With respect to scenario 2, Par has not shown Eagle's optimized manufacturing process is likely to result in a pH reflecting multiple ranges of "variability" added on top of Eagle's in-process specification. (FF¶¶413, 418, 420–422.) The data show the opposite. Dr. Park explained that the data demonstrate that any variability in the in-process, release, and stability measurements is centered around the target 3.50. (FF¶¶397, 420.) There is no basis to tack on all of that variability ***above*** the recorded in-process measurements, as Par proposes. (FF¶¶413, 418, 420–422.) Indeed, even taking into account the full extent of variability identified by Par, the highest release value measured was 3.57 for SVA011, with most measurements being significantly lower. (FF¶414.) Further,

after release, the pH of SVA011 went ***down*** not up. (FF¶416.) Par's cherry-picking of data that purportedly support its analysis, while ignoring data that do not, should be rejected.

Thus, even if the Court looks to Eagle's data, it too shows non-infringement.

IV. PAR CANNOT SHOW EAGLE WILL DIRECTLY OR INDIRECTLY INFRINGE

Par's infringement claims also fail for the independent reason that Par cannot show ***Eagle*** will directly infringe, or induce others to infringe.

A. Eagle Will Not Directly Infringe Par's Patents

Under § 271(a), "whoever without authority makes, uses, offers to sell, or sells any patented invention … infringes the patent." 35 U.S.C. § 271(a). Par does not contend Eagle will directly infringe the '209 Patent, requiring ***administration*** of vasopressin, which Eagle will not do. (FF¶436.) And although Par argues that Eagle itself will directly infringe the '785 Patent, its argument is not credible.

Par's only basis to assert Eagle will directly infringe the '785 patent is its conjecture that "[i]f Eagle were to ***make***[8] batches within the upper end of its release pH specification, it is more likely than not that the pH of vials sold would drift into the infringing range during their shelf-life," and then "Eagle would be a

[8] There is no dispute that Eagle will not "make" a product with a pH of 3.7–3.9, as that would violate its release specification. (FF¶¶353, 438.)

direct infringer (via ***sale*** of infringing products)."[9] (Pl. Br. at 13.) But Par has not provided evidence showing that Eagle likely will sell a product at a time when its pH will have already drifted up to 3.7. (FF¶439.)

"[G]eneral assertions of facts, general denials, and conclusory statements are insufficient to shoulder [plaintiff's] burden." *TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1372 (Fed. Cir. 2002). But that is all Par offers: speculation and conclusory assertions that "Eagle would be authorized to sell [infringing] products at any point during their shelf-life." (P-FF¶120.) Par presented ***no*** evidence at trial regarding: (1) when during the shelf life the pH is likely to rise into the claimed range; (2) when during the shelf life Eagle is likely to sell its ANDA Product; and (3) whether the former will occur before the latter. (FF¶431.)

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[9] Par's assertion is ambiguous, but if it contends Eagle will directly infringe by making and selling a product that is outside the claimed pH range at the time of sale, but which rises into the claimed range after sale, the Federal Circuit has rejected the theory. *See Cross Med. Prod., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1299, 1305 (Fed. Cir. 2005). In *Cross Medical*, the district court endorsed such a theory, finding the sale of an accused device directly infringed claims requiring an "interface operatively joined to said bone," even though the "interface" was created after sale by surgeons implanting the device. *Id*. But the Federal Circuit reversed, holding the defendant did "not itself make an apparatus with the 'interface' portion," and its device "was not sold with the claimed interface," and therefore did not directly infringe the patent. *Id.* at 1310–11. Likewise here, if Eagle's ANDA Product were to rise into the claimed range after sale, it would do so only during storage by third-party hospitals (and only when kept in certain storage conditions), (FF¶¶436–43), which is an argument of indirect infringement. *See Cross Medical*, 424 F.3d at 1312.

Even if Par could somehow show some vials of Eagle's ANDA Product are likely to rise into the claimed pH range (which it cannot, *see* Section III, *supra*), it still has not shown any such vials are likely to have the claimed pH when they are sold or offered for sale, as required to directly infringe the '785 Patent. (FF¶¶437–439.) In fact, the only batch that ever rose into the claimed pH range—SVA001, which was released at the very top of the release specification—only rose into the claimed range at 24 months. (FF¶¶358, 497.) Eagle would not be selling its ANDA Product at 24 months, as the product expires then. (FF¶446.) Without more, there is no basis to conclude Eagle will ever sell or offer to sell a vasopressin product with a pH of 3.7–3.9, and Eagle cannot be held liable for direct infringement.

Thus, Par cannot sustain a claim of direct infringement of the '785 Patent.

B. Eagle Will Not Induce Others To Infringe Par's Patents

Par also cannot show that Eagle will induce others to infringe either Asserted Patent. To succeed on a § 271(b) inducement claim, Par "must show that [Eagle] took an affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement." *Power Integrations, Inc. v. Fairchild Semiconductor*, 843 F.3d 1315, 1332 (Fed. Cir. 2016). In other words, Par must also show that Eagle "possessed ***specific intent*** to encourage another's infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006).

Par has made no such showing. "When the alleged inducement relies on a drug label's instructions, the question is not just whether those instructions describe the infringing mode, but whether the instructions ***teach*** an infringing use such that we are willing to infer from those instructions an affirmative intent to infringe the patent." *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1368 (Fed. Cir. 2017) (internal marks omitted). Eagle's label does not do this. It informs practitioners that the pH of the product will be 3.4–3.6, not pH 3.7–3.9. (FF¶444.) Moreover, Par concedes that "[c]linicians do not test the pH of the products they administer, [] do not know the pH of those products at the time of administration," and thus would not even be aware that they are administrating a potentially infringing product. (Pl. Br. at 27.) Par does not allege, for instance, that Eagle will encourage practitioners to wait until the pH reaches 3.7–3.9 before administration. (FF¶442.)

To the contrary, Eagle has taken deliberate steps to ***avoid*** infringement, which the Federal Circuit has found "establishes, if anything, an intent by [defendant] ***not*** to induce infringement[.]" *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1470 (Fed. Cir. 1990). In *Hewlett-Packard*, the patentee argued a patent license between defendants showed induced infringement, but the Federal Circuit rejected this argument because the agreement also required the parties "to work together to find a way to avoid infringement … [and] develop a

plotter which would not infringe." 909 F.2d at 1470.

Eagle and AMRI's collaboration here is like that in *Hewlett-Packard*. After Eagle learned of SVA001's OOS pH measurement, Eagle and AMRI cooperated to modify the manufacturing process to "ensure the pH remains within the established range during finished product manufacturing and through the proposed shelf life," and thereby to avoid a repeat of SVA001 in the future. (DTX-133.21; FF¶374; *see* Section III.A, *supra*.) By proactively making these changes, Eagle has demonstrated a clear intent to ***avoid*** infringement, not induce it.

Although Par conceded it must show "specific intent," (Pl. Br. at 11), it identifies none. Instead, Par argues that specific intent can be found "by virtue of this lawsuit and any finding of infringement entered by this Court." (Pl. Br. at 28.) In essence, because its direct infringement argument is not credible, Par seeks an induced infringement finding premised on the assumption that the Court will find induced infringement.

The Federal Circuit has already rejected such a circular argument. In *Warner-Lambert*, the patentee argued similarly that, even if the accused infringer "did not have knowledge of the potential for infringing use at the time it filed its ANDA, [] it does now as a result of this lawsuit." 316 F.3d at 1364. The Federal Circuit rejected this, stating that "mere knowledge alone of ***possible infringement*** by others is insufficient to prove inducement." *Id*. It reiterated that the proper

inquiry for inducement is "limited to an analysis of whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed." *Id*. Because the generic manufacturer in that case sought approval only for an unpatented, non-infringing use, the patentee's showing that "about 2.1% of the prescriptions" could nonetheless be used in an infringing manner was insufficient to prove intent because "it defies common sense to expect that [defendant] will actively promote the sale of its approved [product], in contravention of FDA regulations, for a use that (a) might infringe [the] patent and (b) constitutes such a small fraction of total sales." *Id*. at 1365.

Here, Eagle seeks approval for a product with pH 3.4–3.6 at release and throughout its entire shelf life, and has actively taken measures to comply. (FF¶¶334, 361–385.) Eagle's label is consistent. (FF¶444.) Par does not allege (because the data do not show) that a substantial and intentional percentage of Eagle's ANDA Product will go OOS and drift into the claimed range after sale and before use by practitioners. (*See* FF¶¶405–406, 442.) Thus, as was the case with *Warner-Lambert*, it "defies common sense" to expect Eagle will encourage and promote use of OOS product that would infringe, when that alleged infringement will admittedly have no benefit to Eagle or its customers.

For these reasons, Par also has failed to show that Eagle will induce infringement.

V. PAR'S CLAIMS UNDER § 271(a) AND (b) ARE UNSUPPORTED

Par concludes by arguing that, at the very least, it "is entitled to a declaration of infringement under § 271(a) and (b)," and that these claims are now ripe for resolution due to a newfound immediacy of an Eagle launch. (Pl. Br. at 30–31.) Par also seeks for the first time "judgments declaring that Eagle's sale of products released with a pH at pH 3.60 or higher would result in direct infringement of the Asserted Claims," despite never having sought that relief in its Complaint, or in the Pretrial Order, or otherwise before trial. (Pl. Br. at 31.) This is an improper attempt by Par to expand the scope of its patent claims to cover a pH that was already taught by Original Vasostrict's prior art Label. But in any event, Par is wrong for two reasons, either of which precludes Par's requested relief.

First, the Court lacks subject matter jurisdiction over Par's claim for declaratory relief as now presented. Declaratory judgment jurisdiction exists when the "facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). Par has not proved that Eagle has made or will imminently make a batch of ANDA Product with a release pH of 3.60, or that if it did, the batch would rise into the infringing pH range. (FF¶¶414, 424–430, 497.)

Rather, Par concedes that "[n]one of Eagle's optimization/confirmation batches or subsequent batches have been manufactured at the upper limit (*i.e.*, 3.54) of Eagle's current in-process, post-filtration, pH specification." (P-FF¶79.) And even SVA003, the one batch with pH 3.60 on release (which was made using the outdated, uncontrolled manufacturing process) did ***not*** go OOS and into the claimed pH range at ***any*** point over its shelf life. (P-FF¶103; FF¶¶430, 497.) Moreover, since Eagle optimized its manufacturing process, ***all*** release measurements have been between pH 3.45–3.57, (FF¶399), and none have risen to the claimed range (or even close) over their shelf life. (FF¶400.) Thus, Par is not entitled to a declaration that "Eagle's sale of products released with a pH at pH 3.60 or higher would result in direct infringement of the Asserted Claims." (Pl. Br. at 31.)

Second, even if jurisdiction exists over Par's § 271(a) and (b) claims, Par has failed to prove any likelihood of actual infringement based on the ANDA specifications, testing data and the absence of any evidence of direct or induced infringement, as discussed above. And because Par relies upon the exact same evidence for its § 271(a) and (b) claims as for its § 271(e)(2) claim, a finding of non-infringement for the latter should carry to the former.

VI. CONCLUSION

For these reasons, the Court should hold that Par has not met its burden of demonstrating, by a preponderance of the evidence, that Eagle's ANDA Product, once approved, likely will infringe the asserted claims of the Asserted Patents, under 35 U.S.C. § 271(a), (b) or (e), or that Eagle likely will directly or indirectly infringe those claims.

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Respectfully submitted,

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